9-42470

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

August 26, 2003

Via Federal Express

WARNING LETTER
CIN-WL-03-15559

Aaron Malachi Mixon, Chairman &
Chief Executive Officer
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036

Dear Mr. Mixon:

Investigators from the Food and Drug Administration (FDA) inspected your firm's facilities located at 1200 Taylor Street, 899 Cleveland Street, and One Invacare Way in Elyria, Ohio, between March 10 and 25, 2003. This inspection revealed that the medical devices your firm manufactures, such as power wheelchairs and power scooters, are adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820 (QSR) as follows:

1. Failure to establish and maintain adequate procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

   For example, the [redacted] fuseholders used with [redacted] wire in the battery box assemblies were used in an application that was outside of the manufacturer's recommended specifications for these components without adequate validation or verification of this design change based on the application in which these components were used. Specifically, your firm did not adequately validate the ability of the [redacted] fuseholder with [redacted] wire to safely handle current levels above the specified 10 amp rating under normal operating conditions, which will lead to higher operating temperatures. Also, your firm did not adequately validate the ability of the [redacted] fuseholder with [redacted] wire to be safely used in an environment subject to vibration.

In addition, testing that was performed on the wire/fuse/fuseholder assembly was not completed until after these components were used in production.

In another example, the main fuse in the battery box assembly was changed from a 60 amp fuse to an 80 amp fuse with use of a [redacted] wire (per ECN 9903313). The tests performed to study the effects of the 75 – 80 amp DC current on the [redacted] wire were not completed until after the effective manufacturing date of September 7, 1999. The 80 amp fuse and [redacted] wire assembly is used in an application for which it operates at current levels above its rating for short periods of time under the normal operation of the wheelchair and potentially over much longer intervals in the event of a malfunction of a motor or, the control system.

Your firm did not adequately validate the ability of the [redacted] wire to handle operation above its rating. Engineering tests were conducted to verify that the wire insulation was not damaged when subjected to temperature stresses in a lab setting. However, the ability of the [redacted] wire to handle the increased current was not validated for its intended use because the testing your firm performed does not reflect the actual conditions in which this assembly is used (e.g., connected to a battery inside the battery box installed in a wheelchair).

2. Failure to have a complaint procedure that ensures that all complaints involving the possible failure of a device to meet any of its specifications are adequately reviewed, evaluated, and investigated, as required by 21 C.F.R. 820.198(c).

   The FDA Investigator reviewed all of the complaints pertaining to alleged fire-related incidents that Invacare received from October 1, 2002 to March 10, 2003. The majority of these 41 complaints involved smoking caused by a faulty gearbox seal. There was no documentation to show that Invacare investigated and evaluated these complaints to determine whether the smoking gearboxes are a safety concern.

3. Failure to establish and maintain adequate procedures for in-process acceptance activities including inspections, tests, or other verification activities to ensure that specified requirements for in-process product are met, as required by 21 CFR 820.80(c).

   For example, the FDA Investigator observed that an assembler was performing in-process testing of sub-assembly #TS1079992, which is used in manufacturing power wheelchairs. This testing was not performed according to a written procedure, and the test results were not documented.

We acknowledge receipt of Invacare's letters of response dated March 31, 2003, May 9, 2003 (a fax to the FDA Investigator), May 15, 2003, May 20, 2003, and May 21, 2003. In addition, we had a telephone conversation with Invacare representatives on May 14, 2003, during which some of the deficiencies were discussed.

The actions Invacare has taken appear adequate to correct some, but not all, of the deficiencies FDA observed during these inspections. We consider Invacare's responses to be inadequate in the areas identified below.

With regard to item 1 above (FDA 483 observation #3), Invacare responded in a letter dated March 31, 2003, that "The actual problem identified here was that such testing and qualification, though done before implementation of the fuse holder back in 2000, was not documented." As Invacare's March 31st letter acknowledges, documented testing was not performed until several months after the fuseholder had been put into use. In responses dated May 15, 2003 and May 20, 2003, Invacare stated that the manufacturer's recommendations are based upon a continuous load condition and users are instructed to check the requirements based on the specific applications. According to Invacare's responses, tests were performed to verify that the wire gauge size and fuseholder range are adequate for Invacare's specific application. Invacare acknowledged, however, that there were four reports regarding heat deformity and melting of the [redacted] fuseholders. The damaged samples were examined by an outside consultant, [redacted] Invacare stated that the report by [redacted] verifies the use of the [redacted] fuseholder for your application, and that Invacare subsequently decided to switch to a new fuseholder (via ECN #0303057) for use in production in April 2003. The reason stated for this switch was for reliability reasons.

The responses to this issue are inadequate because Invacare has not provided sufficient information regarding the corrective and preventive actions taken to address the root cause and failure mode of the reported heat deformity and melting of the [redacted] fuseholders. Although the report by [redacted] does not consider the incidents of heat deformity and melting of these fuseholders to be a fire hazard, the report does present a potential cause for these incidents. According to the report, vibration may cause weakening of the electrical connection between the fuseholder receptor and the stranded [redacted] wire, which in turn will cause heating under load and certain ambient conditions. It does not appear that Invacare has conducted additional testing to confirm this potential failure mode and to determine the actual root cause and failure mode.

Invacare also has not provided adequate information regarding the corrective and preventive actions taken to address powered wheelchairs that have the [redacted] fuseholders used with the [redacted] wire that are still in commercial distribution. In reference to the heat deformity and melting of the [redacted], your firm states in its letter dated May 15, 2003, that "though there was no perceived safety hazard, Invacare chose to change to a different fuseholder." However, our review of the information and data provided for the damaged [redacted] fuseholders indicates there may be a potential safety hazard. At least three potential reasons can be identified for the increase of the temperature of the fuseholder/wire electrical contacts: 1) this combination of components is being used at an operating current above its rating; 2) the inherent vibration in this application weakens the physical contact thereby reducing the effective cross sectional area of the electrical contact and increasing its electrical resistance; and 3) the oxidation rate of the contact metals is hastened with the deformation of insulation due to vibration, further reducing the effective contact area and further increasing electrical

resistance. Melting and distortion of the fuseholder insulation without blowing the fuse indicate that the fuseholder has failed to perform its intended safety function and has the potential for becoming dismembered. Your firm did not demonstrate that the fuse in one of these melted and distorted fuseholders would eventually open (blow) before a source of electrical ignition (hot spot or electrical arc) could develop at the first physical separation of one of its electrical contacts from the conductor.

With regard to the 80 amp fuse and [redacted] wire assembly, the May 15, 2003 and May 20, 2003 responses indicate that an 80 amp current through this assembly is only sustained for a short period of time. Invacare states that a continuous 80 amp current would not be sustained because the controller software is designed to prevent this condition by limiting the current. Invacare states that if the controller software failed, the controller would shut down with such a continuous load; however, Invacare has not provided adequate validation that the controller would function in this manner. The reports by [redacted] and [redacted] state that the highest temporary current from the battery is 130 amps when the motors are in a stalled condition. This current is only drawn for about 7 seconds after which the controller limits the current to 75 amps. [redacted] suggested that tests be performed to confirm that the 80 amp fuse would trip before the thermal limit of the [redacted] wire is reached, if the controller failed to limit the 130 amp current within the 7 second time limit. Invacare has not provided adequate validation that the 80 amp fuse would trip before the thermal limit of the [redacted] wire is reached if the controller failed to limit the 130 amp current within the 7 second time limit per [redacted] recommendation.

As was mentioned on page 2 of this letter, the testing that Invacare has performed does not appear to adequately demonstrate that the [redacted] wire can withstand a continuous 80 amp in the event of a controller failure. Hence, we believe that your firm's wheelchairs have not been adequately validated for their intended use. The testing that has been provided does not show that Invacare has sufficiently addressed all of the possible effects of the [redacted] wire carrying an 80 amp current until the battery is discharged, including possible effects on other materials or patient in this type of environment. For example, the battery box may provide some thermal insulation such that the [redacted] conductor may experience significantly higher temperatures inside the battery box resulting in possible deformation inside the battery box, and other nearby components could be negatively impacted. Your testing ([redacted] report, pages 2-3) appears to show that the [redacted] conductor can tolerate temperatures up to 255° F (124° C) continuously over its rating with no damage to the wire; however, it does not appear that simulated use testing that addresses using an 80 amp continuous current with a battery harness in place in a wheelchair has been conducted, nor has an adequate justification been provided for not validating this simulated use condition. In addition, the criteria for determining damage to the wire were not documented in the test results. A test in a temperature chamber at 320° F for 30 minutes reported that no damage occurred to the harness. On the other hand the same report stated that the harness became more soft and flexible. Another report stated that the heat shrink material used to bind the wires in the wiring harness together had become soft, some of it had split, and the PTO connector had become soft and pliable.

A loss of insulating qualities can be determined by conducting a dielectric breakdown test as specified in recognized safety standards such as IEC 60601-1 and UL 2601. Invacare has not indicated that any such tests or equivalent tests were conducted.

With regard to item 2 above (FDA 483 observation #2), Invacare's response letter dated March 31, 2003 discussed the steps being taken to correct the deficiency noted regarding the evaluation of complaints involving the possible failure of a device to meet specifications. Whereas Invacare stated that a new procedure would be implemented in April 2003 to describe the process to be followed for such assessments, there was no indication that Invacare plans to perform a safety assessment for the complaints identified by the FDA Investigator regarding power wheelchairs that were smoking due to a gearbox seal leak.

With regard to item 3 above (FDA 483 observation #4), Invacare's March 31, 2003 letter indicated that your firm plans to review all in-process testing or checks to see which ones are effective in identifying problems early in the assembly process and that you will ensure that those identified as worth keeping are properly described in a procedure and documented. The letter further stated that this review may take until year-end to complete. However, there was no indication that Invacare would make an assessment of any corrective actions needed for the products that were produced without testing according to a written procedure and for which there was no documentation that the in-process testing was performed.

Invacare should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies will be advised of the issuance of this warning letter so that they may take this information into account when awarding government contracts.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to Evelyn D. Forney, Compliance Officer, at the above letterhead address.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District